REMARKS

This Amendment and Remarks are believed to fully address all and each issue raised in the Action mailed September 5, 2008. A favorable reconsideration on the merits is respectfully requested.

Claim Status

Upon entry of the amendment, which is respectfully requested, claims 1, 5, 6 and 8-10 are all the claims pending in the application. Claim 1 is amended to more clearly set forth the feature of the invention. Claim 8 is amended to correct typographical errors. The amendment to claim 1 is supported by the specification, for example at page 2, the last line to page 3, the first line, and the abstract.

In this regard, Applicants respectfully submit that, although the present specification does not explicitly describe that the sustained-release composition is delivered to the gastrointestinal tract, it is obvious from the disclosure of the specification describing that technical feature of the subject composition that the drug release rate does not significantly vary with the degree of gastrointestinal motility due to rapid gel hydration without forming a non-gelated core (see page 4, lines 21 to 23 of the specification and the abstract).

Information Disclosure Statements

Applicants thank the Examiner for considering the references listed in the IDS and SB/08 Form filed on November 8, 2004.

Applicants respectfully request that the Examiner initial and return a copy of SB/08 Form filed on March 21, 2007, to make a record that the references listed on March 21, 2007 SB/08 Form were considered by the Examiner.

Response to Rejection Under 35 U.S.C. § 103

In the Office Action, claims 1, 5, 6 and 8-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang *et al.*, U.S. Patent 6,264,981 ("Zhang"), in view of Baichwal, A.R., U.S. Patent 5,846,563 ("Baichwal").

In this regard, the Office asserted Zhang teaches sustained release compositions for oral administration comprising nifedipine.

Baichwal is cited as teaching the ratio of medicament to gelling agent is preferably about 1:3 to about 1:8 (column 2, lines 58-60) and the ratio of inert diluent (carrier) to gelling agent is about 1:8 to about 8:1). The Office asserts that Baichwal teaches dosages of nifedipine as being 20 mg, 30 mg, 60 mg and 90 mg (column 6, lines 66-67). The Office further contends that Baichwal also teaches a ratio of xanthan gum to locust bean gum to be about 1:1.

Vellekoop *et al.*, U.S. Patent 4,765,984 ("Vellekoop"), which the Office relies upon as supporting evidence, is cited as teaching a ratio of sodium alginate to gum which is about 1:1.6 to 2:1. Another supporting evidence, Bowersock *et al.*, U.S. Patent 6,656,470 ("Bowerscok"), is cited as teaching a preferred weight ratio of a cellulose ether to an alginate to be about 1:1 about 1:5.

It is the Office's position that the previously claimed specific proportions of the claimed ingredients are not seen to be inconsistent with the ratios that would have been determined by the skilled artisan in formulation chemistry through no more than routine experimentation, and it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art.

Applicants respectfully disagree.

Zhang, at column 16, claims 22-24, teaches that the dosage forms may be an oral transmucosal patch, a lozenge/troche, a lollipop or a chewing gum. Zhang's composition is in the oral transmucosal patch, not for an gastrointestinal route administration.

As set forth above, the applicant further specified the sustained-release composition recited in claim 1 to be delivered to the gastrointestinal tract where the drug is released at a constant rate following zero order kinetics over 24 hours or more.

Neither Zhang nor Baichwal teaches or suggests a sustained-release composition for gastrointestinal delivery which is capable of releasing a drug at a constant rate following zero order kinetics over a period of 24 hours or more, wherein the composition includes nifedipine and all four (4) components recited in claim 1.

Zhang discloses an oral transmucosal delivery system for instant release of a drug which is administered to the oral cavity and absorbed through the oral mucosal tissues, rather than through the gastrointestinal route.

Also, Applicants respectfully submit that the Office has mischaracterized the teachings of Zhang as Zhang provides a mechanism of controlling drug release by controlling the dissolution and disintegration thereof. On the contrary, Zhang is intended to increase the dissolution and disintegration of a formulation in the oral cavity, which is clearly different from the sustained release of a drug in the stomach and the intestines.

Specifically, the working examples of Zhang clearly show that the drug release pattern of the Zhang's formulation is far from that of zero order kinetics. The formulations described in the working examples of Zhang exhibit a burst release of a drug just after the administration of the drug (T_{max} = about 10 to 20 min) followed by the decrease in the serum concentration of the drug.

Accordingly, one skilled in the art would not be motivated to select the specific four (4) components employed in the subject invention from the numerous dissolution agents described in Zhang in order to obtain the sustained-release composition of the subject invention, which is delivered to the gastrointestinal tract and is capable of releasing the drug therein at a constant rate which follows zero order kinetics over a period of 24 hours or more.

Responding to Applicants' arguments that the formulation of Baichwal fails to release the drug at a constant rate following zero order kinetics for 24 hours or more require a demonstration of zero order kinetics, the Office pointed out the previously presented claims did not require such feature.

In response, Applicants amended claim 1 to more clearly set forth the feature of the invention defined in the claims. Therefore, it is believed that amended claim 1 and its dependent claims are patentably distinguishable from Zhang and Baichwal, and, accordingly, it is respectfully requested that the rejection based on Baichwal be withdrawn.

With respect to claim 10, the Office rejects Applicants' argument that Baichwal fails to disclose the use of HPMC, sodium alginate and propylene glycol alginate, on the grounds that gelling agents such as alginates and HPMC are well known in the art.

However, Applicants draw the Office's attention to the fact that the two components falling within the same category of alginates have opposite effects on the release of a drug in the subject composition, i.e., sodium alginate slows the drug release, whereas propyleneglycol alginate promotes the drug release (see Test Examples 3 and 5 of the subject specification).

Therefore, even assuming that alginates and HPMC have been well known as gelling agents, one skilled in the art would not have been motivated to choose the combinations of the specific components recited in claim 10 (and claim 1 and dependent claims) with a reasonable

expectation of success to reach the currently claimed invention, or have predicted the specific components employed in the subject invention would show the intended results of the present invention.

For the reasons discussed above, it is believed that the rejections are not sustainable and withdrawal is respectfully requested.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588.**

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

Sunhee Lee
Registration No. 53,892

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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